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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,413	02/27/2002	Avraham J. Domb	Q63391	7369

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EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/083,413	Applicant(s) Domb et al.
	Examiner Michele Flood	Art Unit 1651

-- The MAILING DATE of this communication appears on the c ver sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 27, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-34* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-26, drawn to a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue comprising (a) and (b), classified in class 424, subclass 449 or class 424, subclass 725+, for example or class 424, subclass 58, for example.

II. Claims 27-28, drawn to a solid self-bioadhesive composition for a topical application that adheres to the oral mucosal tissue comprising (i) and (ii), classified in class 424, subclass 449 or class 424, subclass 448, for example.

III. Claims 29-31, drawn to a method for the preparation of a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue comprising the steps (iii), (iv) and (v), classified in class 424, subclass 449 or class 424, subclass 434, for example.

IV. Claim 32, drawn to a method for topical oral treatment, classified in class 514, subclass 2.

V. Claim 33, drawn to a method for treating and/or preventing, oral mucositis, aphthous lesions, gingivitis in a patient, classified in class 514, subclass 909.

VI. Claim 34, drawn to a method for reducing the depth of periodontal pockets in a patient, classified in class 514, subclass 900.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the two groups are directed to two different inventions. For instance, the invention of Group I is directed to a composition comprising (a) a therapeutically effective amount of at least one herbal or homeopathic active agent; and (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition, whereas the invention of Group II is directed to a composition comprising (i) a combination of an anti-inflammatory, anesthetic agent and an anti-microbial agent; and (ii) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition. The two different groups comprise materially different ingredients. Different compositions comprising materially different ingredients are not expected to have the same functional effect.

3. Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the three different groups are directed to three different inventions. For instance, the invention of Group

IV is directed to a method for topical oral treatment, whereas the invention of Group V is directed to a method for treating and/or preventing, oral mucositis, aphthous lesions, gingivitis in a patient; and, whereas the invention of Group VI is directed to a method for reducing the depth of periodontal pockets in a patient. These methods are capable of separate manufacture, use or sale, as claimed, and are patentable (novel and unobvious) over each other (though they may be unpatentable because of the prior art) subjects. One would not have to practice the various methods at the same time to practice just one method alone.

4. Inventions I and IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as can claimed in useful in treating different disease conditions, as evidenced by the claims themselves. Moreover, the process for using the product as claimed can be practiced with another materially different product. For instance, in U.S. Patent 4,246,287, Cabardo, Jr. teaches a method for treating periodontal disorders such as gingivitis by topical application of a mixture of potassium alum and sodium bicarbonate powder; in U.S. Patent 6,458,777, Sonis et al. teach a method of reducing or inhibiting oral mucositis comprising administering an inflammatory cytokine inhibitor or a mast cell inhibitor; and, in U.S. Patent 6,325,991, Draheim teaches a method for treating periodontal disease with an inhibitor of secretory phospholipase A2.

5. Inventions I-II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make other and materially different product, as evidenced by the claims themselves.

6. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Michele C. Flood.

MCF

November 1, 2002